



# KANSAS DRUG UTILIZATION REVIEW NEWSLETTER

**Health Information Designs, LLC**

**Fall 2015**

Welcome to the Fall 2015 edition of the "Kansas Drug Utilization Review Newsletter," published by Health Information Designs, LLC (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Program (KMAP).

## Helpful Web Sites

### **KMAP Web Site**

<https://www.kmap-state-ks.us/>

### **KDHE-DHCF Web Site**

<http://www.kdheks.gov/hcf/>

### **KanCare Web Site**

<http://www.kancare.ks.gov/>

## Fee-For-Service (FFS)

### Helpful Numbers

#### **Provider Customer Service (Provider Use Only)**

1-800-933-6593

#### **Beneficiary Customer Service**

1-800-766-9012

#### **KMAP PA Help Desk**

1-800-285-4978

## **In This Issue**

Hepatitis C Guideline Update

Preferred Drug List Updates

New and Upcoming Generic  
Medications

## **Hepatitis C Virus (HCV) Infection**

Hepatitis C is a blood-borne viral infection of the liver that is transmitted through percutaneous exposure to blood. Common modes of transmission include sharing needles to inject drugs, sharing equipment or devices for non-injection drug use, mother-to-infant, sexual exposure, long-term hemodialysis, and unregulated tattoo settings. Sixty percent of acute HCV infections are caused by exposure to the virus through injectable drug use, which is the most important risk factor for HCV infection. For some people, hepatitis C is a short-term illness, but for the majority, 70-85%, it becomes a long-term chronic infection.

Currently, treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies caused by comorbid disease states that cannot be remediated by treating HCV. Despite this, it remains important for clinicians to determine individuals who are at high-risk for complications, both hepatic and extrahepatic. Therefore, based on limited available resources, immediate treatment should be prioritized so that patients at high risk of liver-related complications are treated with the highest priority.

As many emerging treatments for hepatitis C infection are becoming available, guidelines of treatment are changing. The newer regimens are showing higher rates of sustained virologic response (SVR) and increased tolerability. The goal of treatment is SVR, or "virologic cure," defined as the continued absence of detectable HCV RNA for at least 12 weeks after completion of therapy. Patients still have HCV antibodies but no longer have detectable HCV RNA. An FDA-approved quantitative or qualitative nucleic acid test (NAT) is used to detect a level of 25 IU/mL or lower to be considered undetectable. The benefits of an undetectable viral load are the virus no longer being transmitted from person to person, a reduction in symptoms and mortality from severe extrahepatic manifestations, decreased liver inflammation, decreased liver cancer, and a reduced risk of the need for liver transplantation.

There are many variables to consider when choosing a therapeutic regimen for a patient. Treatment regimens differ based on genotype, prior therapy (if any), FDA-approved indications, pre-existing renal or hepatic impairment, HIV coinfection, comorbidities, and compliance; duration may be based on presence or absence of cirrhosis. Initial treatment includes patients who have never been previously exposed to interferon (IFN), peg-interferon (PEG-IFN), ribavirin (RBV), or any direct-acting antiviral (DAA) agent. Retreatment includes patients who have had any exposure to a prior regimen for HCV. Refer to the HCV guidelines for treatment regimens by genotype, duration of therapy, and those regimens that are no longer recommended.

## **Current Approved Agents for HCV Infection**

### Direct-acting Antivirals

Harvoni (ledipasvir 90 mg/sofosbuvir 400 mg) tablets

Viekira Pak (ombitasvir 12.5 mg/ paritaprevir 75 mg/ritonavir 50 mg/dasabuvir 250 mg) tablets

Sovaldi (sofosbuvir) 400 mg tablets

Olysio (simeprevir) 150 mg capsules

Daklinza (daclatasvir) 30 mg and 60 mg tablets

Technivie (ombitasvir 12.5 mg/paritaprevir 75 mg/ritonavir 50 mg) tablets

### Antivirals

Ribavirin (RBV)

### Immunomodulators (PEG-IFN, IFN)

Peginterferon alfa-2b

Interferon alfa-2b

Peginterferon alfa-2a

Interferon alfacon-1

## Hepatitis C Virus (HCV) Infection cont.

### New Direct-acting Antiviral Agents\*

	Daklinza	Technivie
<b>Genotype</b>	Genotype 3	Genotype 4
<b>Age</b>	18 years of age and older	18 years of age and older
<b>Dose</b>	Dosed once daily	Dosed 2 tablets once daily
<b>Therapy Duration</b>	12 weeks of therapy	12 weeks of therapy
<b>Combination Therapy</b>	In combination with Sovaldi	In combination with ribavirin (can be used without ribavirin in treatment-naïve patients unable to tolerate ribavirin)
<b>Important Drug Interactions**</b>	CYP3A drug interactions	CYP3A drug interactions Ethinyl estradiol oral contraceptives
<b>Hepatic Impairment</b>	No hepatic impairment adjustments	Contraindicated in Child-Pugh class B/C; do not use in cirrhosis

### Review and Update of Existing Direct-acting Antiviral Agents\*

	Sovaldi	Harvoni
<b>Genotype</b>	Genotypes 1-4	Genotypes 1, 4, 5, 6
<b>Age</b>	18 years of age and older	18 years of age and older
<b>Dose</b>	Dosed once daily	Dosed once daily
<b>Therapy Duration</b>	Genotype 1 with IFN: 12 weeks Genotype 1 without IFN: 24 weeks Genotype 2: 12 weeks Genotype 3: 24 weeks Genotype 4: 12 weeks Hepatocellular carcinoma: 48 weeks	Genotype 1 treatment-naïve, HCV RNA < 6 million IU/mL: 8 weeks Genotype 1 treatment-naïve, HCV RNA ≥ 6 million IU/mL: 12 weeks Genotype 1 treatment-experienced without cirrhosis: 12 weeks Genotype 1 treatment-experienced with cirrhosis: 24 weeks Genotypes 4, 5, 6: 12 weeks
<b>Combination Therapy</b>	In combination with RBV; also with or without IFN in genotype 1	With or without RBV
<b>Important Drug Interactions**</b>	Amiodarone P-gp Inducers	Amiodarone P-gp Inducers
<b>Hepatic Impairment</b>	No hepatic impairment adjustments	No hepatic impairment adjustments

	Viekira Pak	Olysio
<b>Genotype</b>	Genotype 1	Genotype 1
<b>Age</b>	18 years of age and older	18 years of age and older
<b>Dose</b>	Ombitasvir/paritaprevir/ ritonavir tablet: 2 tablets every morning Dasabuvir tablet: 1 tablet twice daily	Dosed once daily
<b>Therapy Duration</b>	Genotype 1a: 12 weeks (without cirrhosis); 24 weeks (with cirrhosis) Genotype 1b: 12 weeks Liver transplant recipients: 24 weeks.	Treatment-naïve and prior relapse patients: 24 weeks Prior non-responder patients: 48 weeks
<b>Combination Therapy</b>	In combination with RBV (can be used without RBV in patients unable to tolerate RBV)	In combination with RBV and IFN Not FDA approved for combination therapy with Sovaldi
<b>Important Drug Interactions**</b>	CYP3A drug interactions Ethinyl estradiol oral contraceptives	CYP3A4 inducers and inhibitors
<b>Hepatic Impairment</b>	Not recommended in decompensated liver disease; contraindicated in Child-Pugh class B/C	Not recommended in Child-Pugh class C

\*See package insert for full details relating to the medication

\*\*See package insert for full list of drug interactions

## Hepatitis C Virus (HCV) Infection cont.

### Monitoring of Patients after Treatment

#### Patients who achieve SVR

- For patients without advanced fibrosis (Metavir F0-F2), follow-up is the same as if the patient was never infected with HCV.
- For patients with advanced fibrosis (Metavir F3-F4), surveillance for hepatocellular carcinoma with twice-yearly ultrasound testing.
- For patients with cirrhosis, baseline endoscopy to screen for varices. If varices are present, treat and follow up as indicated.
- Assessment for HCV recurrence or reinfection should be done only if the patient has ongoing HCV risk or if unexplained hepatic dysfunction develops.
- If persistently abnormal liver tests develop, assess for other causes of liver disease.

#### Patients who fail to achieve SVR

- Assessment of disease progression every 6 to 12 months, with a hepatic function panel, complete blood count (CBC), and international normalized ratio (INR).
- For patients with advanced fibrosis (Metavir F3-F4), surveillance for hepatocellular carcinoma with twice-yearly ultrasound testing.
- For patients with cirrhosis, endoscopy to screen for varices. If varices are present, treat and follow up as indicated.
- Evaluate for retreatment as effective alternative treatments become available.

#### References:

1. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. Available at <http://www.hcvguidelines.org>. Accessed on November 9, 2015.
2. Centers for Disease Control and Prevention. Viral Hepatitis - Hepatitis C Information. Last updated May 31, 2015. Available at <http://www.cdc.gov/hepatitis/hcv>. Accessed on November 9, 2015.
3. Daklinza (daclatasvir) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Co; July 2015.
4. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; November 2015.
5. Olysio (simeprevir) [prescribing information]. Titusville, NJ: Janssen Therapeutics; November 2014.
6. Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences; August 2015.
7. Technivie (ombitasvir, paritaprevir, and ritonavir) [prescribing information]. North Chicago, IL: AbbVie Inc; July 2015.
8. Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2015.

### HCV Coverage for the Medicaid Population in the State of Kansas

Currently, all of the direct-acting agents listed above require a prior authorization (PA) and can be found on the state website at [http://www.kdheks.gov/hcf/pharmacy/pa\\_criteria.htm](http://www.kdheks.gov/hcf/pharmacy/pa_criteria.htm). With new emerging HCV agents, indications, and warnings, the state of Kansas is in constant review of hepatitis C literature and presents changes to PA criteria in front of the quarterly Drug Utilization Review (DUR) board to approve updates for proper usage, when applicable.

## Updates to the Preferred Drug List

Drug list updated December 1, 2015. Preferred agents listed include the generic formulations, when applicable.

#### Intranasal Antihistamines:

Astepro® and Patanase® are now non-preferred

#### Intranasal Corticosteroids:

Omnaris® and Zetonna® are now non-preferred

#### Long-Acting Opioids:

Butrans®, ConZip®, Embeda®, Nucynta ER®, and Ultram ER® are now preferred

#### Antiherpes Virus Agents:

Valtrex® is now preferred

#### Oral Mesalamine Products:

Lialda® is now preferred

#### Phosphate Binder Agents:

Eliphos® and Phoslo® are preferred

#### Topical Acne Agents:

Acanya®, Aczone®, Atralin®, Avita®, Azelex®, Benzamycin®, Cerisa®, Cleocin-T®, Cleocin-T®, Clindacin ETZ®, Clindacin-P®, Clindagel®, Epiduo®, Ery®, Erygel®, Erythromycin solution, Retin-A®, SSS 10-5®, Sulfacetamide suspension, Sulfacetamide-Sulfur lotion, Tazorac®, Veltin®, Zencia®, and Ziana® are preferred.

## New and Upcoming Generic Medications

### Recently Approved Generic Drugs:

August 2015	September 2015	October 2015
Paliperidone extended-release tablets (Invega) Testosterone topical gel 1.62% (AndroGel) Testosterone topical gel 10 mg per pump actuation (Fortesta Gel) Tretinoin gel 0.05% (Atralin Gel) Tetrabenazine tablets (Xenazine) Rivastigmine transdermal system (Exelon)	Balsalazide disodium tablets (Giazio) Fluvastatin sodium extended-release tablets (Lescol XL) Clozapine orally disintegrating tablets (FazaClo ODT) Pimozide tablets (Orap) Adapalene and benzoyl peroxide gel, 0.1%/2.5% (Epiduo topical gel)	Memantine hydrochloride oral solution (Namenda oral solution) Itraconazole oral solution (Sporanox oral solution)

### Upcoming Generic Drugs:

Generic Name	Brand Name	Anticipated Launch
Aripiprazole	Abilify Discmelt	Second Half 2015
Methylphenidate	Daytrana	Second Half 2015
Aprepitant	Emend	Second Half 2015
Fenofibrate	Fenoglide	October 2015
Frovatriptan	Frova	October 2015
Olopatadine	Patanol	December 6, 2015
Ethinyl Estradiol/Norgestimate	Ortho Tri-Cyclen Lo	December 31, 2015
Dutasteride/Tamsulosin	Jalyn	Fourth Quarter 2015
Dutasteride	Avodart	Fourth Quarter 2015
Imatinib	Gleevec	February 1, 2016
Metformin	Glumetza	February 1, 2016

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